PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 20 APR 2001
WIPO PCT

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
P427416 DJJ/KJR/ghb			
International Application No.	International Filing Date *(day/month/year)*	Priority Date *(day/month/year)*	
PCT/NZ00/00087	2 June 2000	4 June 1999	

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] A01N 43/90, 43/52, 25/02, A61K 31/4184, 31/429

Applicant

NUFARM LIMITED

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☒	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☒	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
26 October 2000	6 April 2001
Name and mailing address of the IPEA/AU	Authorized Officer
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/NZ00/00087

I. Basis of the report

1. With regard to the **elements** of the international application:*

- [X] the international application as originally filed.
- [ ] the description, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the claims, pages , as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the drawings, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

- [ ] contained in the international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: **17, 18, 19, 26-30, 35-38, 43, 44(in part), 45(in part), 46-48, 50, 51 and 52(in part)**

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. **17, 18, 19, 26-30, 35-38, 43, 44(in part), 45(in part), 46-48, 50, 51 and 52(in part) because these claims are of such broad scope that it is not possible to conduct a meaningful search. Thus, no meaningful opinion could be formed.**

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- [ ] restricted the claims.
- [ ] paid additional fees.
- [ ] paid additional fees under protest.
- [ ] neither restricted nor paid additional fees.

2. [ ] This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- [ ] complied with.
- [X] not complied with for the following reasons:

(i) Claims 1-16, 31-34, 39, 40, 44(in part), 45(in part) and 52(in part) are directed to compositions containing levamisole/tetramisole.

(ii) Claims 41 and42 are directed to methods of formulating anthelmintic compositions.

(iii) Claims 20-25, 44(in part), 45(in part), 49 and 52(in part) are directed to benzimidazole compositions.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- [ ] all parts.
- [X] the parts relating to claims Nos. **1-16, 20-25, 31-34, 39, 40-42, 44(in part), 45(in part) and 52(in part)**

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	YES
	Claims **1-16, 20-25, 31-34, 39, 40-42, 44, 45 and 52**	NO
Inventive step (IS)	Claims	YES
	Claims **1-16, 20-25, 31-34, 39, 40-42, 44, 45 and 52**	NO
Industrial applicability (IA)	Claims **1-16, 20-25, 31-34, 39, 40-42, 44(in part), 45(in part) and 52(in part)**	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

This report is based on the following documents identified in the International Search Report:

D1 = US 4395407
D2 = US 3980791
D3 = US 4278684
D4 = EP 224249
D5 = JP 04220398
D6 = JP 52001046
D7 = JP 58021615
D8 = JP 58020622
D9 = JP 07017812
D10 = CN 1194832

NOVELTY (N) and INVENTVE STEP (IS): Claims 1-16, 20-25, 31-34, 39, 40-42, 44, 45 and 52

D1 discloses parasiticidal pour-on compositions comprising (a) from 1-30% by weight of tetramisole and/or levamisole, (b) from 2-15%by weight of phosmet - an insecticide and acaricide, (c) one or more aliphatic carboxylic acids each with a pKa-value comprised between 0.6-6, in a solvent and/or carrier. This composition is considered to anticipate the composition of the present claimed invention **of Claims 1-15, 31-34, 39, 40-42, 44, 45 and 52** which are thus considered not novel and not inventive.

D2 discloses a pour-on composition useful in treating helminthic infestations, comprising tetramisole, levamisole, or a non-toxic addition salt. However, the document does not disclose or teach toward any of the inventions of the present application.

D3 discloses a pour-on composition useful in treating helminthic infestations, comprising (a) tetramisole and/or levamisole, (b) one or more aliphatic carboxylic acids each with a pKa-value of 3-6, and (c) at least one dicarboxylic acid of formula (II). Water and the presence of an aqueous phase are not mentioned, which distinguishes this document from the present application. The inventions of the present application are thus considered novel and inventive in light of this document.

D4 discloses benzimidazoles dissolved in an acid - see pages 13-14. **Claims 20-25** are thus not novel and not inventive in light of this document.

D5 discloses a composition comprising a benzimidazole and an organic acid, including lactic acid. **Claims 20-25** are thus not novel or inventive in light of this document.

CONTINUED ON SUPPLEMENTAL SHEET:

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 1 is not clear with regard to part (iv) "at least water".

Claim 44 is not clear and not fully disclosed in the specification. The scope of the term "pests" is broader in scope than that of "helminths".

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of V (2):

D6 discloses a composition comprising a benzimidazole and an organic acid, including lactic acid. **Claims 20-25** are thus not novel or inventive in light of this document.

D7 discloses a composition comprising a benzimidazole and an organic acid, including lactic acid. **Claims 20-25** are thus not novel or inventive in light of this document.

D8 discloses a composition comprising a benzimidazole and an organic acid, including lactic acid. **Claims 20-25** are thus not novel or inventive in light of this document.

D9 discloses a composition comprising a benzimidazole and an organic acid, including lactic acid. **Claims 20-25** are thus not novel or inventive in light of this document.

D10 discloses a composition comprising 0.05-10% ivermectin, levamisole and albendazole. **Claim 16** is thus not novel or inventive in light of this document.